

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | | |
|-----------------------|--|----------------------|------------|
| In re Application of: | Myriam GOLEMBO et al. | Confirmation No.: | 3940 |
| Application No.: | 10/664,605 | Group Art Unit: | 1646 |
| Filing Date: | September 15, 2003 | Examiner: | |
| For: | METHOD AND COMPOSITION FOR TREATMENT OF SKELETAL DYSPLASIAS | Attorney Docket No.: | 81408-4300 |

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to Applicants' duty of disclosure under 37 C.F.R. § 1.56, enclosed is a Form PTO-1449 containing a total of 38 references for the Examiner's review and consideration. Copies of non-U.S. patent references labeled B1 and C1-C24 are enclosed herewith. Copies of U.S. patent references A1-A13 will be provided if the Examiner so requests.

It is respectfully requested that the references be made of record in this application by the Examiner's completion and return of the enclosed Form PTO-1449. While no representation is made that any of these references may be "prior art" within the meaning of that term under 35 U.S.C. Sections 102 or 103, the enclosed list of references is disclosed so as to fully comply with the duty of disclosure set forth in 37 C.F.R. Section 1.56.

Moreover, while no representation is made that a specific search of office files or patent office records has been conducted or that no better art exists, the undersigned attorney of record believes that the references listed, together with any other references which may have been previously cited by or submitted to the Office, are the closest to the claimed invention (taken in its entirety) of which the undersigned is presently aware, and no art which is closer to the claimed invention (taken in its entirety) has been knowingly withheld.

This Information Disclosure Statement is filed under 37 C.F.R. § 1.97(b), before the latter of three months after the U.S. patent application filing date or prior to the mailing date of a first Office Action on the merits. Accordingly, no fee or certification is required. Should

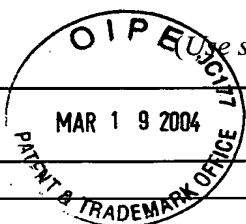
any fees be required, however, please charge such fees to Winston & Strawn LLP Deposit
Account No. 50-1814.

Respectfully submitted,

3/19/09
Date

Rodney J. Fuller
Rodney J. Fuller (Reg. No. 46,714)
For: Allan A. Fanucci (Reg. No. 30,256)

WINSTON & STRAWN LLP
Customer No. 28765
202-371-5904

| | | | |
|--|--|-----------------------|------------------|
| LIST OF REFERENCES CITED BY APPLICANT Form PTO-1449 <i>(Use several sheets if necessary)</i> | | ATTY. DOCKET NO.: | APPLICATION NO.: |
| | | 81408-4300 | 10/664,605 |
|  | | APPLICANT: | |
| | | Myriam GOLEMBO et al. | |
| Sheet 1 of 2 | | FILING DATE: | GROUP: |
| | | September 15, 2003 | 1646 |

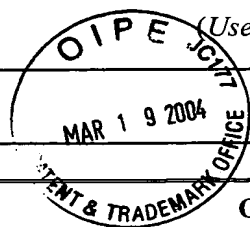
| U.S. PATENT DOCUMENTS | | | | | | | |
|-----------------------|----------|-----------------|---------|------------------|-------|----------|----------------------------|
| *EXAMINER INITIAL | CITE NO. | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
| | A1 | 4,683,195 | 07/1987 | Mullis et al. | 435 | 6 | |
| | A2 | 4,683,202 | 07/1987 | Mullis | 435 | 91.2 | |
| | A3 | 4,965,188 | 10/1990 | Mullis et al. | 435 | 6 | |
| | A4 | 5,336,759 | 08/1994 | Matsuo et al. | 530 | 326 | |
| | A5 | 5,338,759 | 08/1994 | Shechter et al. | 514 | 492 | |
| | A6 | 5,434,133 | 07/1995 | Tanaka et al. | 514 | 12 | |
| | A7 | 5,846,932 | 12/1998 | Lowe et al. | 514 | 9 | |
| | A8 | 5,973,134 | 10/1999 | Matsuo et al. | 536 | 23.53 | |
| | A9 | 6,020,168 | 02/2000 | Matsuo et al. | 435 | 69.4 | |
| | A10 | 6,034,231 | 03/2000 | Tanaka et al. | 536 | 23.51 | |
| | A11 | 2001/0025026 | 09/2001 | Heartlein et al. | 514 | 12 | |
| | A12 | 6,329,375 | 12/2001 | Tang et al. | 514 | 250 | |
| | A13 | 6,344,459 | 02/2002 | Bridges et al. | 514 | 234.5 | |

| FOREIGN PATENT DOCUMENTS | | | | | | | | |
|--------------------------|----|-----------------|---------|---------|-------|----------|-------------|----|
| | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION | |
| | | | | | | | YES | NO |
| | B1 | WO 00/61631 | 10/2000 | WIPO | C07K | 14/58 | | |

| OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.) | | |
|---|---|--|
| C1 | Agrawal, S. et al., "Pharmacokinetics, biodistribution, and stability of oligodeoxynucleotide phosphorothioates in mice," <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 88, pp. 7595-7599 (1991). | |
| C2 | Brandt, R.R. et al., "Neutral Endopeptidase Regulates C-Type Natriuretic Peptide Metabolism But Does Not Potentiate Its Bioactivity In Vivo," <i>Hypertension</i> , Vol. 30, No. 2, pp. 184-190 (1997). | |
| C3 | Chang, P.L., "Microcapsules as Bio-organs for Somatic Gene Therapy," <i>Annals New York Academy of Sciences</i> , Vol. 831, pp. 460-473 (1997) | |
| C4 | Chen, H.H. et al., "C-Type Natriuretic Peptide: The Endothelial Component of the Natriuretic Peptide System," <i>J. of Cardiovasc. Pharmacol.</i> , Vol. 32, Suppl. 3, pp. S22-S28 (1998). | |
| C5 | Chen, H.H. et al., "Natriuretic Peptides in the Pathophysiology of Congestive Heart Failure," <i>Curr. Cardiol. Rev.</i> , Vol. 2, pp. 198-205 (2000). | |
| C6 | Chusho, H. et al., "Dwarfism and early death in mice lacking C-type natriuretic peptide," <i>PNAS</i> , Vol. 98, No. 7, pp. 4016-4021 (2001). | |

| | |
|---|-----------------|
| EXAMINER | DATE CONSIDERED |
| *EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | |

| | | |
|--|-------------------------------------|--------------------------------|
| LIST OF REFERENCES CITED BY APPLICANT Form PTO-1449 <i>(Use several sheets if necessary)</i> | ATTY. DOCKET NO.: 81408-4300 | APPLICATION NO.: 10/664,605 |
| | APPLICANT: Myriam GOLEMBO et al. | |
| Sheet 2 of 2 | FILING DATE: September 15, 2003 | GROUP: 1646 |



| OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.) | | |
|---|--|--|
| C7 | Fingl, E. et al., "Chapter 1--General Principles," in The Pharmacological Basis of Therapeutics 5th edition, MacMillan Publishing Co., Inc., New York, pp. 1-46 (1975). | |
| C8 | Harvey, C.B. et al., "Molecular Mechanisms of Thyroid Hormone Effects on Bone Growth and Function," <i>Molecular Genetics and Metabolism</i> , Vol. 75, pp. 17-30 (2002). | |
| C9 | Kelly, P.A. et al., "Growth Hormone Receptor Signalling and Actions in Bone Growth," <i>Hormone Research</i> , Vol. 55 (suppl. 2), pp. 14-17 (2001). | |
| C10 | Kridel, S.J. et al., "Substrate Hydrolysis by Matrix Metalloproteinase-9," <i>J. Biol. Chem.</i> , Vol. 276, No. 23, pp. 20572-20578 (2001). | |
| C11 | Matsukawa, N. et al., "The natriuretic peptide clearance receptor locally modulates the physiological effects of the natriuretic peptide system," <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 96, pp. 7403-7308 (1999). | |
| C12 | McCarthy, T.L. et al., "Local IGF-I expression and bone formation," <i>Growth Hormone & IGF Research</i> , Vol. 11, pp. 213-219 (2001). | |
| C13 | Mericq, V. et al., "Regulation of Fetal Rat Bone Growth by C-Type Natriuretic Peptide and cGMP," <i>Pediatric Research</i> , Vol. 47, No. 2, pp. 189-193 (2000). | |
| C14 | Murthy, K.S. et al., "Identification of the G Protein-activating Domain of the Natriuretic Peptide Clearance Receptor (NPR-C)," <i>J. Biol. Chem.</i> , Vol. 274, No. 25, pp. 17587-17592 (1999). | |
| C15 | Ohbayashi, H. et al., "Neutral endopeptidase 3.4.24.11 Inhibition Potentiates the Inhibitory Effects of Type-C Natriuretic Peptide on Leukotriene D ₄ -Induced Airway Changes," <i>Clin. Exp. Pharma. Physiol.</i> , Vol. 25, pp. 986-991 (1998). | |
| C16 | Pillai, O. et al., "Polymers in drug delivery," <i>Curr. Opin. Chem. Biol.</i> , Vol. 5, pp. 447-451 (2001). | |
| C17 | Rousseau, F. et al., "Mutations in the gene encoding fibroblast growth factor receptor-3 in achondroplasia," <i>Nature</i> , Vol. 371, pp. 252-254 (1994). | |
| C18 | Schweitz, H. et al., "A New Member of the Natriuretic Peptide Family Is Present in the Venom of the Green Mamba (<i>Dendroaspis angusticeps</i>)," <i>J. Biol. Chem.</i> , Vol. 267, No. 20, pp. 13928-13932 (1992). | |
| C19 | Shiang, R. et al., "Mutations in the Transmembrane Domain of FGFR3 Cause the Most Common Genetic Form of Dwarfism, Achondroplasia," <i>Cell</i> , Vol. 78, pp. 335-342 (1994). | |
| C20 | Suda, M. et al., "Skeletal overgrowth in transgenic mice that overexpress brain natriuretic peptide," <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 95, pp. 2337-2342 (1998). | |
| C21 | Vajo, Z. et al., "The Molecular and Genetic Basis of Fibroblast Growth Factor Receptor 3 Disorders: The Achondroplasia Family of Skeletal Dysplasias, Muenke Craniosynostosis, and Crouzon Syndrome with Acanthosis Nigrans," <i>Endocrine Reviews</i> , Vol. 21, No. 1, pp. 23-39 (2000). | |
| C22 | Van Leeuwen, J.P.T.M. et al., "24,25-Dihydroxyvitamin D ₃ and bone metabolism," <i>Steroids</i> , Vol. 66, pp. 375-380 (2001). | |
| C23 | Yamashita, Y. et al., "Concentration of mRNA for the Natriuretic Peptide Receptor-C in Hypertrophic Chondrocytes of the Fetal Mouse Tibia," <i>J. Biochem.</i> , Vol. 127, pp. 177-179 (2000). | |
| C24 | Yasoda, A. et al., "Natriuretic Peptide Regulation of Endochondral Ossification," <i>J. Biol. Chem.</i> , Vol. 273, No. 19, pp. 11695-11700 (1998). | |

| | |
|---|-----------------|
| EXAMINER | DATE CONSIDERED |
| *EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | |